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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,310	01/21/2000	Gary Stephenson	7922	5677
27752	7590	11/01/2004	EXAMINER	
THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			KRASS, FREDERICK F	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,310

Applicant(s)

STEPHENSON, GARY

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 17-20 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 17-20 and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Preliminary Remarks

The prosecution history of this application has been frustrating for all concerned. The examiner's (false) assertion that calculus is the "underlying cause of dental erosion" has, inadvertently and most unfortunately, greatly added to this frustration. The examiner sincerely apologizes for the error and all confusion generated by same.

Applicant is encouraged to take all steps necessary to recoup fees associated with filing the RCE. The case had to be withdrawn from issue due to issuance of the Ngai decision concurrent therewith, and Applicant graciously helped the examiner by filing an RCE to help streamline prosecution and facilitate consideration of new issues and art. Refund of the filing fees would certainly seem to be appropriate under these circumstances.

Status of Rejections

All prior rejections are hereby withdrawn except for the following.

Claims 11-15, 17-20 and 22-31 were rejected under 35 U.S.C. 102(b) as being anticipated by Kohl et al.

This rejection is maintained. The product and process claims will be addressed separately as follows:

Process Claims

The examiner reiterates his position, stated originally on page 4 of the previous office action, that the recited "method for treating dental erosion" requires only that the beverage be "orally administered" to a mammal, which would occur when an individual consumed the Kohl et al juices. An individual

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consuming one of the fruit juices disclosed by the prior art would inherently be protected from dental erosion caused by that specific beverage, even if he was unaware of the fact. The examiner has not ignored the limitations of Applicant's method of use claims; they are inherently disclosed by the prior art insofar as the claims are currently constructed.

The court in Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (C.A. Fed (Ind.)(2003) has stated that the phrase "in need thereof" provides a ready mechanism to overcome such inherency by distinguishing individuals who are simply exposed to a therapeutic agent from those actually being treated for a specific condition with an "effective amount" of the agent. Accordingly, and as previously suggested, this rejection can be obviated by amending the instant method claims to read:

--- A method for treating dental erosion, comprising orally administering to a mammal in need thereof an effective amount of a beverage... ----

Were this language to be adopted, claims 23-31 would be ALLOWABLE.

Product Claims

Applicant argues:

The prosecution of this case has degenerated to one legal question: does the instruction limitation in the Kit claims, and the use limitation in the method claims lend patentable weight to the present claims? The Applicant asserts that under the Federal Circuit opinions in Gulack and Miller, the instruction and use limitations of the present claims must be given consideration. And when considered in light of the prior art of this case, the claims are patentable.

Applicant further asserts that the instruction and use limitations of the present claims must be given consideration even under the Federal Circuit's more recent decision In re Ngai ___ F3d ___ (Fed. Cir. (2004). It is true that based on the particular facts of Ngai, the Federal Circuit held that the instructions in the kit claims do not lend patentable weight to the claims. But Ngai is distinguishable on the facts. In Ngai, the instructions in the kit claim related to the use of a buffer for normalizing and amplifying an RNA population. But Ngai did not dispute that the prior art contained a kit with instructions for using a similar, if not identical buffer. No such prior art exists in this case.

The PTO, as represented by Technology Center 1600, has apparently chosen to construe the Ngai decision more broadly. As the examiner understands that position, Ngai is to be understood to

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reinforce the holdings of earlier precedent requiring that a label be "functionally related" to its substrate. The label in this case is not: "information" concerning the treatment of dental erosion is not required for the use of, i.e., is not "functionally related to", the instant beverage compositions, which are otherwise identical to those of Kohl et al.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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